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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/686,499 10/11/00 CURTISS

R 3116-1192

EXAMINER

HM12/0620

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SHAHNAN-SHAH, E

ART UNIT	PAPER NUMBER
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1645

DATE MAILED:

06/20/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/686,499	CURTISS, ROY
	Examiner	Art Unit
	Khatol S Shahnan-Shah	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 May 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 11 October 2000 is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) Interview Summary (PTO-413) Paper No(s) _____.
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: _____

DETAILED ACTION

1. Applicant's Information disclosure statement, received January 29 and 30, 2001, papers # 3 and 2 are acknowledged.

Election/Restrictions

2. Applicant's election and amendment of May 7, 2001, paper No. 5 is acknowledged. Claims 23- 44, are canceled and claim 1 is amended.
3. Currently claims 1-22 are pending and under consideration.

Drawings

4. The drawings are objected to by the Draftsperson under 37 CFR 1.84 or 1.152. See attached form PTO 498.
5. The drawings are objected to by the Examiner as failing to comply with 37 CFR 1.84(p)(5) because all figures except figure 1, 2 and 6B are not labeled. Appropriate corrections are required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 3, 6, 11-12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "functional replacement" and "functionally replace" in claims 1 and 12 are unclear, and thus renders the claims indefinite. Specification merely defines some possible embodiments

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but does not define the terms "functional replacement" and "functionally replace" (see specification page 8, line 25-35). It is not clear which functions of the essential enzyme will be replaced by the vector.

Claims 3 and 6 are indefinite for the use of abbreviations for a variety of genes without their full names.

Claim 11 abbreviation "CMV" is unclear. The full name or explanation of the above mentioned abbreviation is required when appears in the claim for the first time.

Claim 14 line 2 abbreviation "DAP" is unclear. The full name or explanation of the above mentioned abbreviation is required when appears in the claim for the first time.

Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nayak et al., (Infection and immunity Vol. 66 No. 8 pp. 3744 –3751, 1998), in view of Curtiss (US Patents Number 5840483 and 6024961)

Claims 1-22 are drawn to an attenuated derivative of a pathogenic microorganism (Enterobacteriaceae) which have an inactivating mutation in a native essential gene and a recombinant complementing gene on a vector (plasmid) encoding a replacement for an essential

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enzyme. And the desired gene product is a bacterial antigen (vaccine). The above product was achieved by the use of the balanced- lethal host-vector system.

Nayak et al. teach an attenuated *Salmonella typhimurium* with *cya* and *crp* gen mutations. Stable expression of a bacterial antigen (*Streptococcus pneumoniae* surface protein A) was achieved by the use of the balanced- lethal host-vector system, which employs an *asd* deletion in the host chromosome to impose an obligate requirement for diaminopimelic acid (DAP). They also used *Asd+* vector pYA3148 or the recombinant plasmid pYA 3193. Nayak et al. do not teach *pur* gene.

Curtiss (US Patent No. 5840483) teaches a genetically engineered strain of *salmonella* (Enterobacteriaceae) characterized by a lack of functioning native chromosomal gene encoding an enzyme which catalyzes a step in the biosynthesis of diaminopimelic acid (DAP). And the second recombinant gene encodes a desired gene product (bacterial antigen) (see claims and figures). In this patent Curtiss does not teach different genes.

Curtiss et al. (US Patent No. 6024961) teach an avirulent immunogenic strain of *Salmonella typhi* having an inactivating mutation in one or more genes comprising of *pab*, *pur*, *aro*, *asd*, *dap*, *nadA*, *pncB*, *galE*, *pmi*, *fur*, *rpsL*, *ompR*, *htrA*, *hemA*, *cdt*, *cya*, *crp*, *phoP*, *phoQ*, *rfc*, *poxA*, *galU*, or a combination thereof. (See claims, figures specially figure 7 and abstract) They also teach a recombinant gene encoding the desired gene product.

It would be *prima facie* obvious to one skilled in the art at the time that invention was made to combine the products and methods taught by Nayak et al. and Curtiss et al. to obtain the instant invention.

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One skilled in the art would be motivated to do this to develop more attenuated strains of pathogenic bacteria, which can serve as delivery vehicles for recombinant antigens and vaccines for a variety of infectious diseases.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached from 7:30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

 6/18/01
Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER